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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,507	10/14/2003	Bernard Andreas	021629-001900US	3531

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
OU, JING RUI	

ART UNIT	PAPER NUMBER
4123	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,507	ANDREAS ET AL.	
	Examiner	Art Unit	
	JING OU	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *4 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-13, and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment filed on 12/06/2007. Claims 1-34 are pending. Claims 1, 11, 21 and 27 are independent. Claims 4, 14, and 21-34 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2, 5-12, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Fischell et al (US Pat. No.: 5,639,274).

In regard to claim 1-2, 5-12, 15-18 and 20, Chermoni discloses:

A) a stent delivery device for delivering a plurality of stent segments to a treatment site, the device comprising: a catheter shaft (124, Fig. 1) having a proximal end and a distal end; an expandable member (balloon, 104, Fig. 7) coupled with the catheter shaft near the distal end; a shuttle (carriage, 605, Fig. 7) disposed coaxially over at least part of the catheter shaft and the expandable member, at least part of the shuttle being radially expandable (Para. [0042]); and a plurality of stent segments (206a, 206b, 206c, Fig. 7) disposed along the shuttle;

B) the shuttle is slidably disposed over at least part of the catheter shaft and the expandable member (Para. [0041]);

C) the stent segments are fixed to the shuttle until they are expanded into a deployed position (Paras.[0041]-[0042]);

D) the stent segments are slidable (Para.[0041]), the device further comprising a stent-pushing member (106, Fig. 7), proximal to the plurality of stent segments.

E) the shuttle further comprises an abutment (barrier, next to 610a, Fig. 7) at or near a distal end of the shuttle for preventing the plurality of stent segments from being advanced beyond the distal end of the shuttle;

Chermoni does not appear to discloses:

A) an axially movable sheath disposed over at least part of the catheter shaft and the expandable member and moving the sheath axially toward the

proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand, thus causing at least one of the plurality of stent segments to expand;

B) sheath is disposed over the shuttle;

C) sheath is adapted to expose a first portion of the expandable member to deploy a first selected number of stent segments;

D) the sheath is adapted to further expose at least a second portion of the expandable member to deploy a second selected number of stent segments. However, Fischell et al explicitly discloses:

A) an axially movable sheath (outer sheath, Fig. 7A) disposed over at least part of the catheter shaft (outer shaft, 22, Fig. 7A) and the expandable member (stent, 15, Fig. 7A) and moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand, thus causing a stent to expand (Col. 6, lines 59-62 and Figs. 7E-7F).

B) the sheath is disposed over the distal portion of the outer shaft of catheter that carries the stent (Fig. 7A);

C) the sheath is adapted to expose a first portion of the expandable member to deploy a first selected number of stent segments (Col. 6, lines 59-62 and Figs. 7E-7F);

D) the sheath is adapted to further expose at least a second portion of the expandable member to deploy a second selected number of stent segments (Col. 6, lines 59-62 and Figs. 7E-7F)

Chermoni and Fischell et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni and Fischell et al before him or her, to modify the stent delivery device of Chermoni to include an axially movable sheath and replace the stent push member of Chermoni by a pusher tube as taught by Fischell et al.

Applicant should note that it is well-known in the art that an axial movable sheath is used to keep a stent to remain unexpanded and prevent a stent from deploying at an undesired location. It is also well-known that a pusher tube is used to push the stent out a sheath or covers.

Therefore, it would have been obvious to combine Fischell et al with Chermoni to obtain the invention as specified in the instant claims.

5. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Fischell et al (US Pat. No.: 7,137,993, B2) as applied to claims 1 and 11 above, and further in view of Shaknovich (US Pat. No.: 5,807,398).

In regard to claims 3 and 13, Chermoni and Fischell et al disclose all the limitations of the claim as taught above but fail to disclose that the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member.

However, Shaknovich explicitly discloses a shuttle (1, Fig. 1) that is fixedly disposed over at least part of the catheter shaft (7, Fig. 1) and the expandable member (8, Figs 1 and 4 and Col. 4, lines 22-31).

Chermoni, Fischell et al, and Shaknovich are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Chermoni, Fischell et al, and Shaknovich before him or her to modify the stent delivery device of Chermoni and Fischell et al to include a shuttle that is fixedly disposed over at least part of the catheter shaft and the expandable member of Shaknovich.

The motivation/suggestion for doing so would have been to be advanced into a patient as a shuttle-balloon catheter assembly (Shaknovich, Col. 11, lines 1-16).

Therefore, it would have been obvious to combine Shaknovich with Fischell et al and Chermoni to obtain the invention as specified in the instant claims.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Fischell et al (US Pat. No.: 5,639,274) as taught in Claim 11, and further in view of Martinez et al (US Pat. No.: 5,593,412).

In regard to Claim 19, Chermoni in view of Fischell et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Martinez et al explicitly discloses valve members coupled with the sheath (51-55, Fig. 2B).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Fischell et al before him or her, to modify the stent delivery device of Chermoni in view of Fischell to include the valve members coupled with the sheath as taught by Martinez et al.

Applicant should note that it is well-known in the art that the valve members coupled with the sheath keeps the stent from premature deployment.

Therefore, it would have been obvious to combine Martinez et al with Chermoni and Fischell et al to obtain the invention as specified in the instant claim.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Fischell et al (US Pat. No.: 5,639,274) as taught in Claim 11, and further in view of Fernandez-Aceytuno (US Pat. No.: 5,735,869)

In regard to Claim 19, Chermoni in view of Fischell et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Fernandez-Aceytuno explicitly discloses valve members (circular constriction, 16, Fig. 1) coupled with a sleeve (12, Fig. 1).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Fischell et al before him or her, to modify the stent delivery device of Chermoni in view of Fischell to include the valve members coupled with the sleeve as taught by Fernandez-Aceytuno.

The suggestion/motivation for doing so would have been to prevent displacement of the apparatus disposed inside the sleeve during the insertion of the catheter into the body vessel (Fernandez-Aceytuno, Col. 4, lines 57-65)

Therefore, it would have been obvious to combine Fernandez-Aceytuno with Chermoni and Fischell et al to obtain the invention as specified in the instant claim.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Fischell et al (US Pat. No.: 5,639,274) as taught in Claim 11, and further in view of Palermo (US Pat. No.: 5,312,415)

In regard to Claim 19, Chermoni in view of Fischell et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Palermo explicitly discloses a sheath with a constricted distal end (104, Fig. 1).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Fischell et al before him or her, to modify the stent delivery device of Chermoni in view of Fischell to include a sheath with a constricted distal end as taught by Palermo.

The suggestion/motivation for doing so would have been to control the discharge of the coil through the catheter sheath distal tip (Palermo, Col. 3, lines 67-68 and Col. 4, lines 1-3)

Therefore, it would have been obvious to combine Palermo with Chermoni and Fischell et al to obtain the invention as specified in the instant claim.

Response to Arguments

Applicant's arguments, filed on 12/06/2007, with respect to the rejection(s) of claim(s) 1-3, 5-13, and 15-20 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made.

Terminal Disclaimer

9. The terminal disclaimer filed on 12/06/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. No.: 7,137,993 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jing Rui Ou whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123